WHAT IS CLAIMED IS:

1. A method for determining a predisposition, or presence of prostate cancer in a patient comprising:

a) contacting a biological sample of said patient with at least one oligonucleotide that hybridizes to a PCA3 polynucleotide selected from the group consisting of:

i) a polynucleotides according to SEQ ID NOs 9, 10 and 13;

ii) a polynucleotide sequence that hybridizes under high stringency conditions to the polynucleotide sequence in i); and

iii) a polynucleotide sequence fully complementary to i) or ii) ; and contacting said biological sample with at least one oligonucleotide that hybridizes with a second prostate specific polynucleotide,

b) detecting in said biological sample an amount of PCA3 and second prostate specific polynucleotides; and

comparing the amount of PCA3 polynucleotide that hybridizes to the oligonucleotide to a predetermined cut off value, and therefrom determining the presence or absence of prostate cancer in the biological sample.

2. The method of claim 1, wherein said second specific prostate specific nucleic acid is selected from the group consisting of: PSA, human kallikrein 2, PSMA, transglutaminase 4, acid phosphatase and PCGEM1 nucleic acid.

3. The method of claim 2, wherein said prostate specific nucleic acid is PSA.

4. The method of claim 3, wherein said PSA sequence hybridizes to human kallikrein 2.

5. The method of claim 1, wherein the amount of PCA3 polynucleotide and of the second specific prostate cancer polynucleotide is determined using an assay selected from the group consisting of:

a) an amplification assay; and

b) a hybridization assay.

6. The method of claim 5, wherein said amplification assay is an *in vitro* RNA amplification method.

7. The method of claim 6, wherein said RNA amplification method is selected from the group consisting of:

a) nucleic acid sequence-based amplification (NASBA);

b) polymerase chain reaction (PCR);

c) transcription mediated amplification assay (TMA); and

d) ligase chain reaction.

8. The method of claim 6, wherein said amplification of PCA3 and said second prostate specific nucleic acid is performed simultaneously.

9. The method of claim 6, wherein said amplification of PCA3 is carried out using a primer pair composed of SEQ ID NOs: 3 and 4.

10. The method of claim 6, wherein said detection is performed by fluorescence, chimiluminescence or colorimetry detection.

11. The method of claim 10, wherein said detection of PCA3 is carried out using acridinium ester compounds.

12. The method of claim 6, wherein said detection of PCA3 is carried out using a molecular beacon.

13. The method of claim 12, wherein said beacon has the sequence set forth in SEQ ID NO: 6.

14. The method of one of claims 6, wherein said second prostate specific nucleic acid is PSA and said amplification thereof is carried out using a primer pair composed of SEQ ID NOs: 1 and 2.

15. The method of claim 14, wherein said detection of PSA is carried out using acridinium ester compounds.

16. The method of claim 14, wherein said detection of PSA is carried out using a PSA molecular beacon.

17. The method of claim 16, wherein said PSA beacon has the sequence set forth in SEQ ID NO: 5.

18. The method of claim 1, wherein said sample contains at least one prostate cell and said at least one cell is collected from said sample prior to step a).

19. The method of claim 18, wherein said nucleic acid is extracted from said at least one prostate cell.

20. The method of claim 19, wherein said nucleic acid is RNA.

21. The method of claim 20, wherein said RNA is extracted using a silica-based method.

22. The method of claims 1, wherein said sample is selected from the group consisting of:

a) urine;
b) blood or fraction thereof; and
c) prostate biopsy.

23. The method of claim 22 wherein said sample is urine.

24. The method of claim 23, wherein said urine is collected following a digital rectal examination, thereby increasing the number of prostate cells in said sample.

25. The method of claim 1, further comprising:

c) repeating steps (a) and (b) using a biological sample from the patient at a subsequent point in time; and

d) comparing the relative amount of said PCA3 polynucleotide detected in step (c) to the relative amount of PCA3 polynucleotide detected in step (b) and therefrom monitoring the progression of the prostate cancer in the patient.

26. The method of claim 1, wherein the detection of the second prostate specific polynucleotide validates a negative result for PCA3 detection.

27. The methods of claim 1, wherein the biological sample is spiked with an internal control IC selected from the group consisting of:

a) purified nucleic acid;

b) cells;

c) viral particules containg target nucleic acids; and

d) organelles.

28. The method of claim 6, wherein RNA is extracted using a target capture method.

29. The method of claim 1, wherein said detection of PCA3 is carried out using chemiluminescent labels in a homogenous detection method.

30. A diagnostic kit for the detection of prostate cancer or the risk of developing same in a patient comprising:

a) at least one container having disposed therein at least one oligonucleotide probe or primer that hybridizes to one of:

i) a PCA3 nucleic acid sequence according to SEQ ID NO: 9, 10 and 13;

ii) a sequence which is fully complementary to i); and

iii) a sequence which hybridizes under high stringency conditions to i) or ii);

b) at least one oligonucleotide probe or primer that hybridizes with a second prostate specific nucleic acid or complement thereof; and

c) reagents enabling a detection of PCA3 and of said second prostate specific nucleic acid when said PCA3 or second prostate-specific nucleic acid sequence is present.

31. The diagnostic kit according to claim 30, wherein the detection reagent comprises a reporter group or label selected from the group consisting of:

a) radioisotopes;
b) enzymes;
c) fluorescent groups;
d) biotin;
e) chemiluminescent groups; and
f) dye particles.

32. The kit of claim 30, wherein said PCA3 nucleic acid and said second prostate specific nucleic acid are amplified simultaneously in the same container.

33. The kit of claim 30, wherein the detection of said PCA3 nucleic acid and said second prostate specific nucleic acid is performed in the same container.

34. The kit of claim 30, further comprising an internal control (IC) as well as a primer, and/or probe, and/or reagent for the amplification, and/or hybridization, and/or detection of said internal control.

35. The kit of claim 34, wherein said IC is selected from the group consisting of:

a) purified nucleic acid;
b) cells;

c) viral particules containg target nucleic acids; and

d) organelles.

36. A kit for assessing the presence of prostate cancer or the risk of developing same in a patient comprising:

a) a first primer pair specific for amplifying a PCA3 nucleic acid associated with prostate cancer present in a patient sample;

b) a second primer pair specific for amplifying a second prostate-specific nucleic acid; and

c) reagents enabling a detection of PCA3 and of said second prostate specific nucleic acid amplification products when said PCA3 or second prostate-specific nucleic acid sequence is present.

37. A method for detecting prostate cancer in a human patient, comprising:

a) performing an *in vitro* nucleic acid amplification assay on a biological sample of said patient or extract thereof using a first primer pair which is specific to a prostate cancer specific PCA3 sequence and a second primer pair which is specific to a prostate specific nucleic acid sequence; and

b) detecting said PCA3 sequence and said prostate specific nucleic acid sequence,

wherein, a detection of said PCA3 nucleic acid sequence or a level thereof correlates with a risk of developing prostate cancer or to a presence of prostate cancer in said patient, and wherein an absence of detection of said PCA3 nucleic acid sequence or lower level thereof in said sample

validates an absence of prostate cancer or a lower risk of developing same, when said second prostate specific nucleic acid is detected.

38. The method of one of claim 1, wherein said nucleic acid amplification is carried-out in real time.

39. The method of claim 37, wherein said detection is performed by fluorescence, chimiluminescence or colorimetry detection.

40. The method of claim 8, wherein said amplification of PCA3 and said second prostate specific nucleic acid is performed simultaneously in one container.